

## **SUBCHAPTER 16: DENTAL RADIOGRAPHIC INSTALLATIONS**

### **7:28-16.1 Scope**

- (a) This subchapter establishes the requirements for dental radiographic installations.
- (b) No person shall operate or permit the operation of x-ray equipment used in the practice of dentistry unless the equipment and installation meet the applicable requirements of this subchapter.
- (c) The provisions of this subchapter are in addition to and not in substitution for the applicable provisions of N.J.A.C. 7:28- 1 through 3,5, through 8, 13 and 19.

### **7:28-16.2 Definitions**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Cephalometric device” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

“Certified components” means components of x-ray systems which are subject to the regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J- Radiological Health.

“Certified unit” means an x-ray system which has only certified components.

“Coefficient of variation” or “C” means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = \frac{s}{\overline{x}} = \frac{1}{\overline{x}} \sqrt{\frac{\sum_{i=1}^n (x_i - \overline{x})^2}{n - 1}}$$

where s = Estimated standard deviation of the population.  
X = Mean value of observations in sample.  
X = ith observation sampled.  
n = Number of observations sampled

“Control panel” means the x-ray system component and operational controls that include the indicators for x-ray tube voltage (kVp), tube current (mA), timer setting and beam on.

“Diagnostic type protective tube housing “ means an x-ray tube housing so constructed that the leakage radiation measured at a distance of one meter (39.37 inches) from the source does not exceed 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum continuous rated tube potential.

“Kilovolts peak” (see “peak tube potential”).

“kV” means kilovolts.

“kVp” ( see “peak tube potential”).

“Image receptor” means any device such as, but not limited to, a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where a device is provided to preselect portions of the image receptor, the term “image receptor” shall mean the preselected portion of the device.

“Leakage radiation” means all radiation emanating from the diagnostic source assembly except the useful beam. Leakage radiation also means radiation produced when the exposure switch or timer is not activated.

“mA” means milliamperere.

“mAs” means milliamperere second.

“Multiple dental radiographic tube installation” means an installation in which one control panel may energize more than one x-ray tube.

“Peak tube potential” means the maximum value of the potential difference across the x-ray tube during an exposure.

“Primary protective barrier” (see “protective barrier”).

“Protective barrier” means a barrier of radiation absorbing material used to reduce radiation exposure. The types of protective barriers are as follows:

1. “Primary protective barrier” means the material, excluding filters, intercepting the useful beam for protection purposes to reduce the radiation exposure so that it does not exceed two milliroentgens in any one hour.
2. “Secondary protective barrier” means a barrier sufficient to attenuate the stray radiation to reduce radiation exposure so that it does not exceed two milliroentgens in any one hour.

“Radiation (ionizing)” means any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, by interaction with matter.

“Qualified individual” means an individual who meets at least one of the following criteria for diagnostic x-ray equipment:

1. Certification by one of the following agencies in the specialty listed:
  - i. The American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics;
  - ii. The American Board of Health Physics in Comprehensive Health Physics;
  - iii. The American Board of Medical Physics in Diagnostic Imaging Physics or Medical Health Physics;
  - iv. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to li or iii above; or

- v. Certification by other national certifying boards which may be recognized by the Commission on Radiation Protection where the person seeking recognition as a qualified individual has petitioned the CORP in writing and where the CORP has issued a written determination that the certification in question meets the criteria of a qualified individual pursuant to this subchapter;
2. A bachelor's degree from an accredited college in biology, chemistry, radiation sciences, physics, engineering, or mathematics and at least five years of professional technical experience in the field of radiological physics or in the use of medical or dental ionizing radiation-producing equipment;
3. A master's or doctorate degree in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least two years of professional technical experience in the field of radiological physics or in the use of medical or dental ionizing radiation-producing equipment; or
4. Ten years of professional technical experience in the field of radiological physics or in a radiation protection activity. At least five years of the required health physics experience shall have been with medical or dental ionizing radiation-producing equipment.

"Scattered radiation" means radiation that, during passage through matter, has changed in direction or in energy.

"Secondary protective barrier" (see "protective barrier").

"Source-to-image distance" or "SID" means the distance from the radiation source to the center of the input surface of the image receptor.

"Source-to-skin distance" or "SSD" means the distance between the radiation source and the skin of the patient. It is also known as the target-to-skin distance.

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, the technique factors are peak tube potential in kV and quantity of charge in mAs;
2. For field emission equipment rated for pulsed operation, the technique factors are peak tube potential in kV and number of x-ray pulses;
3. For CT x-ray systems designed for pulsed operation, the technique factors are peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulse per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4. For CT x-ray systems not designed for pulsed operation, the technique factors are potential in kV, scan time in seconds, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent ; and
5. For all other equipment, the technique factors are peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

“Uncertified unit” means an x-ray system comprised of components that are not subject to the regulations promulgated under Public Law 90-602, the Radiation Control Act of 1968, 21 Code of Federal Regulations, Chapter 1, Subchapter J- Radiological Health.

#### 7:28-16.3 Dental radiographic equipment

- (a) A person shall not operate or permit the operation of ionizing radiation-producing equipment used in the practice of dentistry unless the equipment meets the requirements listed below:
  1. A diagnostic type protective tube housing shall be provided on the x-ray equipment.
  2. Diaphragms or cones shall be used to collimate the useful beam and shall provide the same degree of protection as the diagnostic type protective tube housing.
  3. For intraoral radiography, the diameter of the useful beam at the end of the cone in contact with the patient shall be no greater than seven centimeters (cm) (2.75 inches) when the source- to-skin distance is 18 cm (seven inches) or more. At SSD's less than 18 cm (seven inches), the diameter of the useful beam at the minimum SSD shall be no greater than six cm (2.36 inches).
  4. A cone or spacer frame shall provide a source-to-skin distance of not less than 18 cm (seven inches) when the x-ray unit operates above 50 kVp or not less than 10 cm (four inches) when the x-ray unit operates at or below 50 kVp.
  5. All machines purchased, donated, or otherwise obtained after July 1, 1969, shall be equipped with open end cones.
  6. The amount of total filtration permanently in the useful beam shall meet the minimum half-value layer (HVL) specified in the following table:

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TABLE 1  
TABLE OF HALF-VALUE  
LAYERS FOR DENTAL UNITS

X-ray tube voltage (kilovoltage peak)		
D Designed Operating Range (kVp)	Measured operating potential (kVp)	Minimum half-value layer(HVL) (mm of Al)
Below 50	30	1.5
	40	1.5
	50	1.5
50 to 70	60	1.5
	70	1.5
	71	2.1
Above 70	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

7. For certified units, the x-ray tube voltage (kilovoltage peak) measured operating potential shall meet the manufacturer's specifications.
8. The exposure control switch shall be of the dead-man type.
9. The exposure control switch shall be provided with a timer that terminates the exposure after a preset time or preset exposure.
10. The exposure control switch button when depressed shall not energize the x-ray tube when the timer is in the "zero" or "off" position.
11. The exposure control switch shall be arranged to allow the operator to stand at least 1.83 meters (six feet) from the patient and well out of the path of the useful beam or to stand behind a protective barrier.
12. The x-ray control panel shall provide visual indication when-ever x-rays are produced.
13. For certified units, a signal audible to the operator shall be provided to indicate that the exposure has terminated.
14. For certified units, the coefficient of variation of the timer reproducibility shall not exceed 0.05 measured at any specific combination of technique factors.

15. For uncertified units, the coefficient of variation of the timer reproducibility shall not exceed 0.07 measured at any specific combination of technique factors.
16. For certified units, the timer accuracy shall meet or exceed the manufacturer's specifications. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value.
17. For certified units, the coefficient of variation of the radiation exposure reproducibility shall not exceed 0.05 measured at any specific combination of technique factors.
18. For uncertified units, the coefficient of variation of the radiation exposure reproducibility shall not exceed 0.07 measured at any combination of technique factors.
19. For uncertified units, the following requirements for radiation exposure linearity shall be met when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:
  - i. for equipment having independent selection of x-ray tube current (mA), the average ratios of exposure to the indicated milliamperere-seconds product [(C/kg/mAs) or mR/mAs] obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is:  $[X1 - X2] < 0.10(X1 + X2)$ ; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube settings.
  - ii. For equipment having a combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure to the indicated milliamperere-seconds product [(C/kg/mAs) or mR/mAs] obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is:  $[X1 - X2] < 0.10(X1 + X2)$ ; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.
20. For certified units, the requirements for linearity is as follows:
  - i. For equipment that allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliamperere-seconds product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:  $[X1 - X2] < 0.10(X1 + X2)$ ; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at each of two consecutive tube current settings or at two tube current settings differing by no more than a factor of two where the tube current selection is continuous.

- ii. For equipment having selection of x-ray tube current exposure time product (mAs), the average ratios of exposure to the indicated milliamperere-seconds product [C/kg/mAs (or mR/mAs)] obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:  $[X1 - X2] / 0.10(X1 + X2)$ ; where X1 and X2 are the average C/kg/mAs ( or mR/mAs) values obtained at each of two consecutive mAs selector settings or at two mAs settings differing by no more than a factor of two where the mAs selector provides continuous selection.\*

21. the mechanical support of the tube head and the cone shall maintain the exposure position without movement, unless the diagnostic type protective tube housing movement is a designed function of the x-ray system (for example, as in panoramic units).

#### 7:28-16.4 Multiple dental radiographic tube installations

- (a) No person shall use x-ray equipment in a multiple dental radiographic tube installation set up or cause it to be used unless the following requirements are met:
  - 1. It shall be possible to activate only one dental radiographic tube at any one time.
  - 2. Where two or more radiographic tubes are controlled by one exposure switch, the dental radiographic tube which has been selected shall be clearly indicated prior to initiation of the exposure. For certified units only, there shall be an indicator on both the x-ray control and at or near the dental radiographic tube housing assembly which has been selected.
  - 3. It shall be possible to energize a dental radiographic tube from an exposure switch located at a specific dental radiographic tube's remote station only when that specific dental radiographic tube is selected.
  - 4. It shall be possible to energize a dental radiographic tube from the main control panel exposure switch only when that specific dental radiographic tube is selected.

#### 7:28-16.5 Cephalometric radiographic installations

- (a) No person shall use x-ray equipment or cause it to be used to perform cephalometric radiographic procedures unless the following requirements are met:
  - 1. The x-ray field in the plane of the image receptor shall not exceed each dimension of the image receptor by more than two percent of the source-to-image distance, when the axis of the x-ray beam is perpendicular to the plane

of the image receptor. In addition the center of the x-ray field shall be aligned with the center of the image receptor to within two percent of the SID, or there shall be a device provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

2. The x-ray unit used for cephalometric radiographs shall meet all the requirements of this subchapter with the exception of N.J.A.C. 7:28-16.3(a)3 and 7:28-16.6.

#### 7:28-16.6 Panoramic radiographic installations

- (a) No person shall use any panoramic radiographic unit or cause it to be used unless the following requirements are met:
  1. The x-ray field in the plane of the image receptor shall not exceed each dimension of the image receptor by more than two percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within two percent of the SID or there shall be a device provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
  2. These units shall meet all the requirements of this subchapter with the exception of N.J.A.C. 7:28-16.3(a)3 and 7:28-16.5

#### 7:28-16.7 Structural shielding

- (a) No person shall operate or permit the operations of x-ray equipment used in the practice of dentistry unless the following requirements are met:
  1. Permanent structural shielding and protective barriers shall be used to ensure that no person other than the patient being x-rayed receives a radiation dose in excess of two milliroentgens in any one hour.
  2. When dental x-ray units are installed in adjacent areas of the same room, such units shall not be used simultaneously unless protective barriers are provided and used in the area between the units when necessary to comply with the radiation exposure limits in N.J.A.C. 7:28-6.

#### 7:28-16.8 Radiation safety surveys

- (a) No person shall operate or permit the operation of x-ray equipment used for dental radiography unless the installation meets the following requirements:
  1. The registrant of a dental ionizing radiation-producing machine shall ensure that a qualified individual performs or supervises the performance of a

radiation safety survey of the environs and submits a copy of the radiation safety survey report to the Department within 60 days of the date the machine is acquired. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available for review by the Department during any inspection;

2. The registrant of a dental ionizing radiation-producing machine shall ensure that a qualified individual performs or supervises the performance of a radiation safety survey of the environs when changes have been made to shielding, equipment, or equipment location which affect the radiation levels of the environs. A copy of the survey report shall be submitted to the Department within 60 days of the date of such change. The registrant shall maintain the original survey report for as long as the machine is registered plus one year and shall make the original survey report available for review by the Department during any inspection; and
3. The minimum requirements for the information to be included in the radiation safety survey report are as follows:
  - i. The name of the registrant of the installation as it appears on form VRH-001, address, telephone number, and room location of the unit;
  - ii. The New Jersey Registration Number, if available.
  - iii. The manufacturer, model number, generator serial number, control panel serial number, tube manufacturer, tube serial number, and tube housing number;
  - v. The date of survey;
  - vi. The survey instrument manufacturer, model number, and date calibrated;
  - vii. A diagram or floor plan of the area indicating the x-ray tube location, exposure switch location, normal operator position, lead shielding if present, wall, floor, and ceiling construction, labeling of all areas adjacent to the exposure room including those above and below, and labeling of all areas as to occupancy and use;
  - viii. Records of the measurement of radiation exposure with a suitable phantom in the average patient position. Measurements shall be taken at the operator's position and all nearby locations which are normally occupied. For each measurement the kVp, mA, exposure time, instrument reading and correction made to the instrument reading (such as energy response, calibration, etc.) shall be recorded; and

- ix. Exposure rates at each measured location shall be converted into Coulombs/kilogram/week or mR/week. Records shall include all assumptions of workload, use and occupancy factors used in the calculations.

#### 7:28-16.9 Operating criteria

- (a) No person shall operate a dental ionizing radiation- producing machine in such a manner as to expose human beings unless such person is a licensed practitioner or holds a valid license issued by the Department pursuant to N.J.A.C. 7:28-19 and the Radiologic Technologist Act, N.J.S.A. 26:2D-24 through 36.
- (b) A person shall operate a dental ionizing radiation-producing machine in a manner consistent with the scope of practice defined on that person's license issued by the Department pursuant to N.J.A.C. 7:28-19.

#### 7:28-16.10 Operating procedures

- (a) All persons who operate or permit the operation of dental radiographic equipment shall comply with following operating procedures:
  - 1. No individual other than the patient being x-rayed shall be in the path of the useful beam;
  - 2. During each exposure the operator shall stand at least 1.83 meters (six feet) from the patient or behind a protective barrier;
  - 3. The film shall not be held by the dentist, the operator, or the assistant during any radiographic exposure;
  - 4. The diagnostic type protective tube housing and the cone shall not be hand held during exposures;
  - 5. Fluoroscopy shall not be used in dental examinations; and
  - 6. The registrant shall provide personnel monitoring equipment to and require that it be worn by each individual who enters a controlled area and receives or is likely to receive a dose in excess of 25 millirems in any period of seven consecutive days.
    - i. Each personnel monitoring device shall be assigned to and worn by only one person.
    - ii. Records of radiation exposure derived from the personnel monitoring device shall be kept in accordance with the requirements of N.J.A.C. 7:28-8.

- iii. The registrant shall keep the personnel monitoring records at the facility. These records shall be kept in accordance with the requirements of N.J.A.C. 7:28-8. These records or true copy of same shall be produced for review by the Department during an inspection, and shall be submitted to the Department upon request.
- iv. The personnel monitoring records shall be available to the employees.